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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,348	06/07/2001	Kathleen L. Horwath	RB-125 RI	9095

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,348

Applicant(s)

HORWATH ET AL.

Examiner

Hope A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the Office Action mailed December 3, 2003 on June 10, 2004 is acknowledged.
2. Claims 1, 3, 8-9, 19 and 29 have been amended. Claims 1-34 are pending. Claim 1-32 are under examination.
3. The following objections and rejections are or remain applicable:

Claim Objection

4. Claims 2, 10-13, 15 and 17-19 are objected to because of the following informalities:
 - (a) Claim 2 is objected to as the transitional phrase "is", is missing from the claim where the claim recites "wherein said solvent selected from the group consisting of".
 - (b) For clarity, it is suggested that claims 10 and 11 are combined to clarify the "conditions that are needed to eliminate non-thermal hysteresis protein induced recrystallization inhibition" recited in claim 10. Note however, that claim 11 recites "said conditions in saline" and claim 10 recites "under conditions". See also claim 12.
 - (c) For clarity claim 13 should be amended to recite "wherein changes to the ice crystal grain size over time is monitored by photomicroscopy, digital or video imaging",

in stead of " wherein monitoring of ice crystal grain size changes over time is by photomicroscopy...".

- (d) For clarity it is suggested that "mlgs" in claim 15 is spelled out to accurately convey the intended meaning (see also claim 17 for "PBS, THP and mlgs" and claim 19).
- (e) For consistency claim 17 should be amended to remove "and/or" and recite only one term.
- (f) Note that claim 18 appears to have an extra parenthesis in line 4, please clarify. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-32 remain rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

- (a) Claim 1 is ambiguous with the phrase "and or" as this gives the claim two different interpretations. It is suggested that one term is used.

The claim remains indefinite as the recrystallization inhibition is unclear as to what is being recrystallized.

Claim 1 remains indefinite as to determining the presence, relative concentration and activity of thermal hysteresis proteins because it appears the present method

refers to ice crystal formation especially since the last step is a mental interpretation and not a physical step *per se* and does not correlate ice crystal grain size with "presence, relative concentration and/or activity".

Step 1 of the method remains indefinite because it does not recite that the proteinaceous composition is thermal hysteresis the protein recited in the preamble and in view of claim 4. The dependent claims hereto are also included in this rejection.

- (b) Claim 2 remains indefinite for the recitation of "or other isoosmotic inorganic or organic solutions" as this is open ended and undefined.
- (c) Claim 4 lacks antecedent basis as it depends from claim 1 which recites "determining the presence, relative concentration and/or activity of thermal hysteresis proteins" and claim 4 requires that the activity of the protein is known. The dependent claims here to are also included.
- (d) Claim 6 provides a Markush listing of "proteinaceous compositions which are inconsistent with the preamble of independent claim 1, see for example in claim 6,"cell culture products, uncharacterized plant products etc., when the method is geared towards determining presence/activity/concentration of a thermal hysteresis protein.
- (e) Claim 7 is indefinite as to "unknown functional antifreeze protein activity". How is what is stated as unknown assessed in the claim?
- (f) Claim 8 as amended is indefinite for the recitation of "...composition includes T_m 12.86" because it is unclear what else is included. It is suggested that the term is deleted and replaced with "has a".

Art Unit: 1653

- (g) Claim 9 lacks antecedent basis for the recitation of "the protein content" as this is not recited in claim 2. It is suggested that the claim is amended to recite "wherein said proteinaceous composition has a protein content less than....".
- (h) Claim 26 remains indefinite with respect to "known characterized parameters experimentally measured", as the metes and bounds of the claim are undefined as to what parameters and how measured. Known to whom? (see also claims 4, 27).
- (i) Claim 30 remains indefinite because the term "high annealing temperature" is a relative term. The term high temperature is not defined by the claim or the specification as no standards are provided to delineate the requisite degree.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1653

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C 103(a).

7. Claim 1 is rejected under 35 U.S.C. 103(a) as unpatentable over Olien (Ann. Rev. Plant Physiology, vol. 18, pages 337-408, 1967) in view of Warren et al. (U.S. Patent No. 5,118,792).

Olien disclose plants that survived the thermal stress of freezing and used the plant extracts (proteinaceous composition) to test for antifreeze properties. The method used by Olien involves monitoring the thermodynamics and kinetics of ice crystal growth in a film during a refreezing process in the presence and absence of the test extract (page 396). In addition, freezing is performed followed by thawing about three fourths (partial thaw), then the sample is then refrozen slowly. This is a measure of recrystallization inhibition. Freezing is also performed followed by thawing about three fourths, then the sample is then refrozen rapidly. This is a form of monitoring thermal hysteresis. Olien does not explicitly teach a method for determining the presence of the hysteresis protein, however, the activity is monitored. Here, Warren et al. disclose screening antifreeze polypeptides by monitoring inhibition of ice crystal growth via refreezing on a cooled metal block, the splat assay (column 4, lines 48-62 and example 3).

Art Unit: 1653

One of skill in the art at the time the invention was made would have been motivated to use the method for monitoring antifreeze properties such as those taught by Olien or Warren et al. because a person of skill in the art would reasonably use available tools to monitor such processes. Additionally, Warren et al. provide motivation to find antifreeze proteins in an organism that exhibits freeze tolerance, to mitigate the damages associated with recrystallization. Hence it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use any available method to screen for antifreeze proteins.

8. Applicant's amendment filed June 10, 2004 has been considered but were not persuasive. Note that the phrase "and or" has been objected to as the claim cannot read both ways, only one term should be recited in the claim. Upon due reconsideration new objections have been made to clarify the claimed invention.

Regarding the rejections under 35 U.S.C. 112, second paragraph, applicant states that the slash mark has been removed between the phrase "and or", however, the phrase with the removal of the slash mark requires clarification as the claims should only recite one term, as both together produces a different meaning.

It is noted that applicant state that the term "ice" has been inserted in claim 1. However, putting ice in the method step does not clarify the preamble thus the issue remains.

Applicant's comments with regard to the last step in the method not being a method step *per se* is not convincing. Applicant states that the invention provides a

Art Unit: 1653

quantitative assay and points to claims 13, 14 and 16-25, however, claim 1 need to stand on its own (see page 13 of the response). As stated above, the preamble of the claim does not provide support for the "proteinaceous composition" being the thermal hysteresis protein". Applicant's comments have been considered, however, as the claim was not amended to provide support for the terminology the rejection remains. The term lacks clear antecedent basis.

As applicant discussed the rejections over claims 4 and 6 together with claim 1 these claims will also be addressed herein. Regarding claim 4 the preamble of claim 1 states "...method for determining the presence, relative concentration and or activity of thermal hysteresis proteins". Applicant state that the method determines the presence of the thermal hysteresis protein which may have know activity as defined by claim 4 or unknown activity as defined by claim 7. However, the plain language of the preamble does not support applicant's statements. The method is directed to determining activity for the protein, thus, claim 4 lacks clear antecedent basis.

Claim 6 recites the Markush listing: antifreeze polypeptides, antifreeze glycopeptides, recombinant synthetic antifreeze polypeptides analogs, synthetic antifreeze glycopeptide analogs, cell culture products, activators, recombinant bacterial products, recombinant products, uncharacterized plant products and transgenic plant products", which is inconsistent. Applicant state that claim 6 defines the various proteinaceous compositions encompassed by the invention method and that the rejection should be withdrawn. Applicant's statement did not clarify how listing such as

"activators, recombinant products, uncharacterized plant products, cell culture products" are consistent with the claimed method.

Claim 2 remains rejected because applicant's statement on page 13 was not persuasive. Applicant state that Examples 1 to 5 described in the specification support inclusion of these terms. However, the issue raised doesn't address support but clarity.

The rejection over claim 7 remains. Applicant's statements on page 14 of the response is noted. The term antifreeze protein means a protein that inhibits the formation of ice crystals, therefore, the phrase "unknown functional antifreeze protein activity" is indefinite. Furthermore, the question asked is: how is what is stated as unknown assessed in the claim? There are no method steps to address this and applicant's statements did not resolve the issues raised.

Note that claims 8-9 as amended necessitated a new ground of rejection for the reasons stated above. Note also that the rejection over claims 26 (see also claims 4 and 27 regarding this issue) remains as applicant did not address the issue raised, instead pointed to support for the terms used in the specification.

The rejection over claim 30 remains. Applicant on page 14 points to sections of the specification to indicate that "higher annealing temperatures are used". However, the limitations of the specification cannot be read into the claim. In addition, the claim does not give a reference point, for example a baseline temperature to start with or what is considered "higher" than the baseline temperature. No upper or lower limits are provided. Therefore, for the reasons stated above the rejections of record remains.

Regarding the rejection under 35 U.S.C. 103(a) applicant state on page 15 of the response that claims 1-32 have been rejected under this statute, however, that is incorrect only claim 1 has been rejected. Applicant's arguments presented on pages 16-17 have been considered, however, are not persuasive. Applicant on page 16 agrees with statements made of the relevance of the cited prior art, however on page 17 indicate that the Splat assay has faults because it lacks specificity for antifreeze protein for example. However, under 35 U.S.C. 103 a mere teaching or suggestion is what is required, which applicant is in agreement that the reference has the teaching. Thus, the combined teachings of the reference by Warren and Olien render the claimed invention in the instant claim 1 as obvious. Some of the statements made by applicant addresses limitations of claims not rejected under this statute, which have not been addressed as the rejection is only over claim 1. The above response is deemed sufficient with regard to claim 1. Therefore, the rejection of record remains.

Conclusion

9. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 1653

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

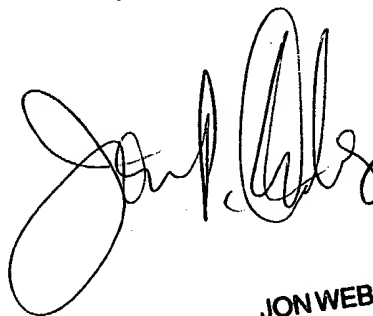
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1653

Hope A. Robinson, MS

HR
8/25/04

Patent Examiner

A handwritten signature in black ink, appearing to read "Jon Weber", with a long horizontal line extending to the right.

JON WEBER
SUPERVISORY PATENT EXAMINER